

VIRGINIA STANDARDS AND PROTOCOLS FOR COMPREHENSIVE HARM REDUCTION PROGRAMS

The purpose of this document is for Virginia Department of Health (VDH) to establish standards and protocols for approval by the Secretary of Health and Human Resources and the Secretary of Public Safety and Homeland Security as required by the passage of House Bill 2317 during the 2017 General Assembly session, [Code of Virginia Section 32.1-45.4](#). This change in the *Code of Virginia* authorizes the Commissioner of Health, during a declared public health emergency, to establish and operate comprehensive harm reduction (CHR) programs that include the provision of sterile and proper disposal of used hypodermic needles and syringes. These standards identify requirements for CHR programs, while the protocols focus on program implementation plans. Because of the importance of local support to the success of these interventions, flexibility is necessary to ensure programs are implemented in a manner consistent with community expectations while adhering to the minimum requirements. To meet this need, VDH will issue guidance documents that support best practices and share lessons learned from localities with established programs.

STANDARDS FOR CHR PROGRAMS

Standard 1—CHR programs are required to develop a time-phased work plan with process measures that demonstrates the program's ability to:

- reduce the spread of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and other bloodborne diseases;
- reduce the transmission of bloodborne diseases through needle stick injuries to law-enforcement and other emergency personnel; and
- provide information regarding addiction recovery treatment services to individuals who inject drugs.

Standard 2—CHR programs are required to identify the communities/localities in which they will provide services. Program operations must be limited to these identified localities where VDH concurs there is a risk of transmission of, or increases in the transmission of, HIV, viral hepatitis, or other blood-borne diseases as a result of injection drug use.

Standard 3—CHR programs are required to demonstrate readiness of the communities/localities in which they will operate. Specifically, programs must provide documentation demonstrating the following:

- support of the local governing body;
- support of law enforcement; and
- programmatic administrative capacity, including relevant service delivery experience; adequate financial resources for program operation; ability to collect and report data, protect confidential information, facilitate access to health care and behavioral health care services for program participants, and develop, implement, document, and maintain a process for community engagement.

Standard 4–CHR programs are required to provide appropriate disposal of used hypodermic needles and syringes.

- Programs must collect and dispose of used needles and syringes in accordance with federal, state, and local laws and regulations. Programs are responsible for ensuring that they research and abide by these requirements. References to assist with this process will be posted on the VDH website.
- Programs will use clearly labeled, rigid, puncture-resistant containers specifically designed for sharps disposal when collecting needles and syringes from participants.
- Programs must provide written proof (e.g., contract, purchase order) of an agreement with the entity that serves as their disposal service for these items before providing services (before or at the time of the pre-operational site visit).
- Programs must track and report disposal metrics.

Standard 5–CHR programs must provide sterile hypodermic needles and syringes and other injection supplies at no cost to participants.

- Programs must obtain and distribute single-use, medical-grade, sterile hypodermic needles and syringes appropriate for substances injected by their participants.
- Programs must provide quantities sufficient to ensure that needles, syringes, and other injection supplies are not shared or reused.
- Programs must track and report distribution metrics.

Standard 6–CHR programs must ensure reasonable and adequate security of program sites, equipment, and personnel. (“Personnel” is used throughout this document to refer to paid staff, paid or unpaid interns, and unpaid volunteers providing services through an approved CHR program).

- Programs must submit a security plan to VDH.
- Programs must offer local law enforcement the opportunity to review their security plan.

Standard 7–CHR programs must be able to verify that a hypodermic needle, syringe, or other injection supplies were obtained from their program.

- Programs must develop a documentation process that shows an individual is a program participant.

Standard 8–CHR programs must be able to verify which personnel the program authorizes to purchase, transport, distribute, and collect hypodermic needles and syringes.

Standard 9–CHR programs must directly provide the following services in addition to distribution of sterile needles and syringes and disposal of used hypodermic needles and syringes:

- individual harm reduction counseling that addresses actions and behavioral changes that reduce or eliminate use of drugs, injuries caused by drugs (e.g., overdose, tissue damage), and transmission of infections via sex and injection drug use;

- educational materials that inform participants about prevention and treatment (these materials must reinforce harm reduction counseling described above and include information about where and how participants can access substance use disorder treatment);
- condom distribution; and
- supplies (e.g., opaque bags) that allow discreet transport of syringes, condoms, etc., out of the program site; alcohol skin wipes that reduce other infections (e.g., cellulitis, endocarditis), and bandages to reduce the potential for blood exposure after injection.

Standard 10–CHR programs must provide the following services, either directly or through a documented referral process, with a verification feedback mechanism:

- overdose prevention education and kits that include naloxone;
- substance use disorder treatment;
- mental health services;
- social services;
- testing for HIV, HBV, HCV, tuberculosis (TB), and sexually transmitted diseases (STDs);
- hepatitis A and B vaccinations;
- HIV pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP);
- health insurance enrollment assistance; and
- medical care/treatment for HIV, HBV, HCV, STDs, TB, and common complications of injecting (e.g., skin infections, cellulitis, endocarditis).

Standard 11–CHR programs must establish policies and procedures that demonstrate compliance with these standards and protocols.

Standard 12–CHR programs must report data required by VDH on a quarterly basis.

PROTOCOLS

Protocol I. Application and approval process for entities seeking authorization to operate a CHR program

- 1) Localities experiencing or at increased risk for transmission of blood-borne infections due to injection drug use were identified through an analysis of the following criteria:
 - a) HIV and hepatitis disease morbidity
 - b) Drug overdose deaths
 - c) Prescription opioid volume
 - d) Buprenorphine-prescribing potential
 - e) Prevalence of treatment for drug overdose
 - f) Emergency Medical Services utilization for drug overdose
 - g) Administration of naloxone
 - h) Substance-use disorder admissions to behavioral health facilities
 - i) Arrests for drug possession or sales, or other drug-related crimes

- j) Poverty level
 - k) Unemployment rate
- 2) Analysis of these criteria to identify localities that VDH categorizes at increased risk will be conducted on an annual basis. Analysis will be conducted more frequently if routine surveillance (e.g., increases in overdose deaths) indicates increased risk in a particular community. For a current list of eligible localities, visit <http://www.vdh.virginia.gov/disease-prevention/eligible-localities/>. *This hyperlink will be live when this document completes final approval.*
 - 3) Entities in these localities that are able to meet all standards and abide by all protocols may submit an application to operate a CHR program to VDH.
 - 4) The application must include a time-phased work plan with process measures that describes how the CHR program will meet the objectives specified in Standard 1. The plan must specify timing and frequency of CHR counseling and required services.
 - 5) The application must include a security plan that specifies:
 - i) Location (physical address for fixed sites, closest intersection for mobile sites) and hours of operation of all service delivery sites;
 - ii) Description of how entity will securely store, collect, and transport hypodermic needles and syringes;
 - iii) Mechanism (e.g., signage, participant handout) used to inform participants that the CHR site is a drug-free environment, including the parking and exterior areas of the site.
 - iv) How the entity will adequately staff service delivery (with at least two personnel on-site while program is serving participants).
 - v) What mechanism the CHR program will use to identify personnel authorized to purchase, transport, distribute, and collect hypodermic needles and syringes. Issuance of a personnel identification card with agency name and address, “Comprehensive Harm Reduction Program Personnel,” and individual’s name and personnel records documenting card distribution will suffice for this purpose.
 - vi) Entity’s personnel policies and training plan that includes but is not limited to:
 - (1) Education on HIV/HBV/HCV transmission, prevention, counseling and testing such as [Virginia HIV AIDS Resource and Consultation Centers’ Facts and Fundamentals](#) or equivalent courses.
 - (2) Infection control and exposure management compliant with
 - (a) [Occupational Safety and Health Administration’s Bloodborne Pathogens Standard \(29 CFR 1910.1030\)](#)
 - (b) [Centers for Disease Control and Prevention’s \(CDC\) Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care](#)
 - (3) Entity’s procedures for preventing and managing personnel’s or participants’ inadvertent exposure to blood in a manner that may transmit infection (e.g., via needle stick injury) in compliance with [current CDC recommendations](#).
 - 6) The application must demonstrate the level of community readiness by providing the following from each locality in which it proposes to provide services:
 - a) Letter of support from the locality’s governing body (such as the mayor, city council, or board of supervisors);
 - b) Letter of support from the locality’s law enforcement agency (sheriff’s office or police department) that acknowledges receipt of the security plan;

- c) Letter of support from the VDH health district (if the applicant entity is not a health district);
 - d) Letters of support from agencies that will accept referrals of participants in need of services required in Standard 10; and
 - e) Description of how the applicant will develop, implement, document, and maintain a process for community engagement that may include a community advisory board.
 - f) The applicant is encouraged to provide additional documentation supporting the level of community readiness that may include support letters from coalitions, businesses, parent groups, drug courts, educational institutions, religious organizations, and other stakeholders.
- 7) The application must demonstrate programmatic administrative capacity by including the following:
- a) Organizational chart that includes positions that will provide CHR services;
 - b) Budget and funding source that may be used for harm reduction services (including purchase of hypodermic syringes and needles since federal funds may not be used for this purpose);
 - c) Description of related health and/or behavioral health services currently provided by the applicant and number of years these services have been provided;
 - d) Description of experience collecting and reporting data; and
 - e) Description of current practices used to protect confidentiality of clients, records, data and [signed verification of receipt and assurance of VDH Division of Disease Prevention \(DDP\) Security and Confidentiality Policies and Procedures.](#)
- 8) VDH has established a Harm Reduction Review Team comprised of subject matter experts, epidemiologists, and senior leadership. This team will receive and review applications and convene as frequently as needed to ensure applications are reviewed in a timely manner and the Health Commissioner can issue an authorization letter within 45 days of application receipt.
- 9) VDH staff will perform a pre-operational site visit to applicants approved by the Harm Reduction Review Team. This visit will provide an opportunity to validate application information, perform any additional assessment needed, and offer technical assistance to ensure successful implementation.
- a) If the site visit findings are favorable, the Health Commissioner will issue an authorization letter that will allow the entity to provide CHR services. This step will be completed within 45 days of VDH's receipt of the entity's application.
 - b) VDH will then establish a memorandum of agreement (MOA) with the applicant to document that it is an affiliated organization with which VDH contracts. The applicant may begin providing CHR services after all parties sign the MOA.
 - c) VDH will repeat a site visit within 45 days of the start of services to ensure programs are operating under the established standards and protocols. Regular site visits (at least every six months), announced or unannounced, will be performed throughout the period during which the program is operating.

Protocol II. CHR program operations

- 1) Enrolling participants in the CHR program
 - a) Individuals who are 18 years of age and older, inject substances, and lack reliable access to sterile needles/syringes may enroll in the program.

- b) At the first visit, CHR program personnel must, at a minimum, collect the following information: name, age, gender, and zip code of residence.
 - c) Prior to first provision of sterile needles and syringes, assess current injection behavior and needs:
 - i) Substance(s) injected and route of administration (to determine gauge/type of needles and syringes needed);
 - ii) Frequency of injection (to determine the number of syringes to distribute);
 - iii) Prior experience with injecting (to determine harm reduction counseling and educational needs).
 - d) By the time of first provision of sterile needles and syringes, the CHR program must provide the participant unique documentation to verify he/she receives injection equipment from the program. An identification card with agency name and address, "Comprehensive Harm Reduction Program Participant," and an individual unique identifier that the agency can link to the participant's name via confidential program records will suffice for this purpose.
 - e) The program will provide CHR counseling and required services as specified in its approved application. The program will maintain documentation that demonstrates counseling and services are provided as required. VDH will review documentation during subsequent site visits.
- 2) Disposal of used hypodermic syringes and needles
- a) Programs will use clearly labeled, rigid, puncture-resistant containers specifically designed for sharps disposal when collecting needles and syringes from participants.
 - b) Programs must provide written proof (e.g., contract, purchase order) to VDH of an agreement with the entity that serves as their disposal service for used hypodermic needles, syringes, and other medical waste before providing services (before or at the time of the pre-operational site visit).
 - c) CHR program personnel and participants must receive instructions on safety precautions for carrying and handling of needles, syringes, and other sharps.
 - i) Instruct participants to recap all their own needles/syringes after use and before transport. Personnel and participants should never recap syringes used by anyone else. If participants' syringes are uncapped upon return, they may still dispose of them in the available sharps containers.
 - ii) During encounters with first responders, instruct participants to notify first responders of the presence of used injection equipment before contact occurs.
 - iii) Personnel must avoid handling used injection equipment or the containers they arrive in. Participants must place their used injection equipment in the CHR site's designated sharps container at each visit.
 - d) CHR sites must have the following safety equipment available during exchange operations:
 - i) puncture-resistant utility gloves
 - ii) latex gloves
 - iii) disinfectant that can destroy blood-borne pathogens in a container (e.g., spray bottle) and appropriate for disinfecting surfaces after a spill
 - iv) forceps or tongs
 - e) For protection against needle-sticks, personnel are required to wear clothing that minimizes exposed skin, including long pants and closed footwear.

- f) Needle-disposal areas should have adequate lighting and be free of clutter or objects that may interfere with safe disposal of needles and syringes. Place large sharps containers on a stable flat surface and keep level at all times. Personnel should never hold sharps containers during disposal.
 - g) Participants should retrieve injection equipment that falls outside of sharps containers and place it in the sharps container. If this is not possible, personnel should use tongs to retrieve used injection equipment that falls outside the container.
 - h) NEVER fill sharps containers beyond the manufacturer's fill line. Containers should never be more than 3/4 full.
 - i) Personnel and participants should never insert their hands into sharps containers or forcibly push used injection equipment down into containers.
- 3) Provision of hypodermic needles and syringes and other injection supplies
- a) During visits to the CHR program, personnel must work to establish rapport with participants. Focus attention on the participant's needs in an environment that is welcoming, respectful, and supportive of program participants.
 - b) The CHR program must provide sufficient quantities of sterile needles and syringes to ensure that needles, syringes, and other injection supplies are not shared or reused. Use the frequency of injecting and visits to the CHR site to determine the number of needles and syringes provided.
 - c) Harm reduction counseling, supplies (condoms, opaque bags, alcohol skin wipes, band-aids, etc.), and educational materials should be offered to participants at every visit.
 - d) Documentation of all services provided must be included in a log or individual participant record.
 - e) CHR programs must establish local policies and procedures that demonstrate compliance with these standards and protocols.

Protocol III. Records and data reporting requirements

- 1) Agencies must maintain adequate documentation to verify personnel and participants' relationship to the CHR program and meet VDH reporting requirements.
 - a) Agencies must maintain documentation of personnel assigned to CHR responsibilities, specifically those authorized to purchase, transport, distribute and collect hypodermic needles and syringes. CHR programs must report the number of authorized personnel to VDH on a monthly basis.
 - b) Agencies must identify which participant record process they will utilize.
 - i) Establish or utilize an existing individual, confidential healthcare record for each participant.
 - ii) Alternatively, CHR programs may keep a master confidential participant log that assigns an individual unique identifier to each participant and matches that identifier to the participant's name. Programs will then keep a separate log of services delivered, recording date, and service units by unique identifier.
- 2) CHR programs will be required to report data, on a quarterly basis, to VDH, which may include the following indicators: (The required data elements will be finalized and established via MOA with each CHR. VDH can provide technical assistance to support data collection when necessary.)
 - a) Number of personnel authorized to purchase, transport, distribute and collect hypodermic syringes and needles;

- b) Number of new participant cards issued
- c) Unduplicated number of participants served
- d) Number of participant visits
- e) Number of sterile needles/syringes distributed
- f) Number of used needles/syringes collected - estimated by having participants provide a count of the number they are depositing in the sharps containers or by weighing sharps containers. Personnel are prohibited from handling used needles/syringes, and therefore should not attempt to directly count those being returned.
- g) Number of participants who received harm reduction counseling, education or related materials
- h) Number of condoms distributed to participants
- i) Number of participants who received an overdose prevention kit containing naloxone
- j) Number of participants referred for or provided mental health services or substance use disorder treatment (e.g., group or individual therapy, case management, detoxification services, medication assisted treatment) who attended at least one appointment
- k) Number of participants referred for or provided social services (e.g. assistance with accessing food, shelter, benefits, adult or child protective services) who attended at least one appointment;
- l) Number of participants tested for HIV and the number with a positive test result
- m) Number of participants tested for HCV and the number with a positive test result
- n) Number of participants referred or tested for HBV, TB, or STDs
- o) Number of participants newly prescribed HIV PrEP
- p) Number of participants newly prescribed HIV nPEP
- q) Number of participants referred for or provided medical care/treatment for HIV for the first time or after a gap in care greater than 12 months who attended at least one appointment
- r) Number of participants referred for or provided medical care/treatment for HCV for the first time who attended at least one appointment
- s) Number of participants newly enrolled to health insurance.